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Hybrid simulation compared to manikin alone in teaching pelvic examinations: A randomised control trial.

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Precis: Hybrid simulation compared to manikin alone improves competence in pelvic examinations at undergraduate level

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Abstract:

Introduction: Performing a pelvic examination is a core skill for all medical undergraduates.

The use of hybrid simulation, manikin with patient actress, to attain technical and communication skills competencies and to improve the quality of care we offer women, has not been compared to other teaching methods before. Outcome measures were technical skills, communication skills and confidence in completing a pelvic examination.

Methods: A cluster randomised control trial with balanced randomisation was conducted over an academic year. Forty eight medical students at North Bristol NHS Trust who completed an eight week obstetrics and gynaecology attachment were recruited. Clusters were randomly assigned for initial training on hybrid or manikin only models and attended an end of attachment Objective Structured Clinical Assessment.

Results: Outcome data was received for 43/48 students (89.5%). Following the objectively structured clinical examination, the hybrid trained cohort had higher technical scores (mean 23 (95% CI: 20.1 to 25.8) vs 16.7 (CI: 14.7 to 18.6); mean difference 6.3, CI 3.0 to 9.6) and communication skills scores (mean 22.6 (CI: 21.2 to 23.8) vs 15.9 (CI: 14.4 to 17.3); mean difference 6.7, CI 4.8 – 8.5) compared to the manikin only trained participants. The hybrid intervention showed a larger effect on communication skills scores than technical skills; (0.74 Vs 0.51). Confidence in undertaking future pelvic examinations were similar in both the control and intervention groups; ($p = 0.10$, $r = 0.18$).

Conclusions: This study demonstrates the value of hybrid simulation compared to manikins alone in improving the short term acquisition of competence in simulated pelvic examinations at an undergraduate level. Future research should focus on whether hybrid models lead to long-term acquisition of skill and comparison of these models with other innovative methods such as clinical teaching associates.

Introduction:

Students experience anxiety when undertaking pelvic examinations.¹ Male medical students particularly report reduced clinical opportunities²⁻⁴ and have lower performance scores during structured clinical assessments.⁴ This variation in experience between genders may be a contributing factor to the increasing proportion of women who now train as Obstetricians and Gynaecologists.⁵⁻⁷ The students' experience of medical specialties at undergraduate level can also significantly affect competency and future career aspirations.^{8,9}

Although the majority of medical undergraduates will not pursue a career in gynaecology, specialty doctors such as surgeons, emergency department practitioners and family doctors will be faced with clinical situations where the need for a pelvic examination will arise. For women not eligible for cervical cancer screening and for those who do not routinely attend, a speculum examination to investigate atypical bleeding patterns may provide the first diagnosis of cancer. Furthermore, 20% of pregnancies result in a miscarriage and for the women whose first presentation with haemorrhage is to the Emergency Department, exsanguination can swiftly occur if a speculum examination is not expedited. Passing a speculum, taking a smear and performing a pelvic examination are therefore core skills for all medical undergraduates, regardless of their career aspirations.¹⁰

Determining educational methods which best support pelvic examination training is vital to the learner, the teacher and the patient. To reduce patient discomfort or harm and to improve patient safety and experience, many practical skills can be effectively learnt with simulation models (manikins) before clinical application. Bench model training for pelvic examinations has

been shown to be both reliable and valid.¹¹⁻¹⁴ What these models cannot offer is the opportunity to practice communication with patients. Poor communication is a key factor in up to 70% of complaints and litigation cases.¹⁵⁻¹⁶ Hybrid simulation (combining a manikin with a patient actor) has been shown to be effective for practising skills which are usually taught separately (procedural and communication)¹⁷ and is superior to didactic lectures in obstetrics.¹⁸ Previous studies however have not compared hybrid models to training with manikins alone in the practice of pelvic (gynaecology) examinations and have relied on self-assessment rather than an objective external review of the students' performance.¹⁸

This study aimed to compare, using a randomised design and assessors blinded to the method of training, hybrid simulation to standard training with manikins alone. The primary outcomes were gynaecological technical and communication skills ability whilst the secondary outcome was confidence in undertaking future gynaecological examinations.

Method:

This was a cluster RCT with balanced randomisation (1:1) and blinded outcome assessment. The study was conducted over a full academic year (2013-2014) and eligible participants were recruited from North Bristol Academy and NHS Trust two weeks prior to their Reproductive Healthcare clinical attachment. Four successive cohorts of 12 students each were allocated to the Academy. Students were excluded if they had previously undertaken pelvic examinations.

Ethical approval was granted by the University of Bristol Faculty of Medicine and Dentistry Committee for Ethics in September 2012 (Ref no 111279). Students were emailed by the university, rather than the research team, two weeks before attending their clinical attachment to allow time to read the participant information sheet and to reduce coerced participation.

Student groups were randomly assigned to intervention or control. Cluster randomisation was chosen to prevent contamination of intervention effects from one cohort to the other, to enhance application of evidence by the whole student cohort and for administrative reasons. An independent researcher, not associated with the project or location where the training was undertaken, generated a computerized random allocation sequence. The allocation was revealed to the lead researcher after recruitment, one week before the initial training workshop for each cluster, to facilitate organisation of equipment. The lead researcher did not take part in the initial training or the final assessment.

Each participant completed a demographic questionnaire, which was developed by the authors. This recorded age, gender, desire to specialise in Women's Health, status as a UK or international student, English as a first language and number of undergraduate communication skills workshops attended. On the first day of their clinical attachment, all participants attended a tutorial which covered gynaecological history taking and the demonstration of an abdominal examination, use of a Cusco's Speculum, bimanual examination and swab taking. This session lasted one hour and was taught with an Adam Rouilly manikin (GYN-TRAINER, ASM 4400) by an experienced gynaecologist and medical educationalist to all four clusters. The

presentation slides were developed from the Royal College of Obstetrics and Gynaecology (RCOG) 2002 Examinations Guideline.¹⁹

Each participant then undertook an abdominal, speculum and vaginal examination, followed by smear and swab taking on the Adam Rouilly manikin. Experienced Gynaecology doctors (Registrar grade) who had completed training posts in Postgraduate medical education were recruited as tutors for this workshop; they were not involved in enrolment or assessment. The tutors used a Crib sheet formulated from the RCOG Examinations Guideline¹⁹ (see Appendix S1) and attended a training session prior to the workshop. The learning objectives included the ability to obtain informed consent, to be able to explain the clinical examination process in layman's terms, and to be aware of clinical safety, patient's needs and dignity. The participant training sessions lasted two hours. In the intervention (hybrid) group, a patient actress sat behind the manikin (Figure 1) and was given the same crib sheet and training session as the tutors. If participants did not interact with the 'patient', she would prompt them by indicating pain or asking about follow up. In the manikin group, there was no patient actress, just the manikin. All participants were given feedback by the tutors which focused on their technical and communication skills ability, in relation to the learning objectives on the Crib sheet. Feedback was also provided by the patient actress in the hybrid trained cohorts.

Following the initial training session, all participants scored their levels of confidence in undertaking future gynaecology examinations using a six point Likert scale (adapted from Arora *et al*²⁰ – Appendix S2) and a survey adapted from the DREEM validated questionnaire²¹ outlining their enjoyment, value and confidence building in the training method used.

After this initial training session, all students undertook an eight week clinical attachment in obstetrics and gynaecology. During this period they all completed at least five speculum and bimanual vaginal examinations. On the last day of the attachment, participants attended an objectively structured clinical examination (OSCE) which was the primary outcome measure. The same scenario was given to all participants; a 25 year old woman had presented to the Emergency Department with abdominal pain, a temperature and offensive discharge. They were asked to undertake a gynaecological examination on the Adam Rouilly model from the initial session and complete any relevant investigations with the equipment provided (Figure 2).

The assessors (patient actress and 'examiner'), were senior registrar gynaecology doctors who had completed training posts in postgraduate medical education. The assessors were not involved in the initial training session and were masked to the method of training. A hired actress was not used for the assessment due to cost. A standardised scoring form to assess technical and communication skills (primary outcome) was used for assessment, adapted from the Kneebone *et al*, 2006²² and RCOG validated assessment questionnaires²³ (see Appendix S3 for the scoring form: items 1-3 & 10-11 for communication scores and items 4 to 9 for technical scores). To improve the consistency of the marking, training of the assessors was completed prior to the structured examination, each participant was double marked and the first participant in each cluster was marked jointly by all of the assessors.

On completion of the assessment, participants were asked to score their levels of confidence in undertaking future gynaecological examinations (secondary outcome) using the same

questionnaire from the initial training session, and were separated from those who had not yet undertaken the assessment.

Statistical methods:

A sample size calculation estimated 10 participants would be needed in each cluster; assuming a 15% improvement in scores (from Pickard *et al*²⁴), with alpha at 0.05% and power at 90%. The forty eight students allocated to North Bristol Trust were all approached to allow for loss to follow up or ineligibility. Descriptive statistics described patient demographics, parametric data analysis was performed using a Student t-test and the Mann-Whitney U Test for non-parametric data. A multivariate regression model was used to assess if the training effect was dependent upon previous communication skills experience or gender. The size of the educational effect was assessed using Cohen's standardised effect size. Stata v13.1 was used for all analyses.

Results:

Four cohorts of 12 medical students were eligible for cluster randomisation. One student from blocks one and four were transferred to another academy a week prior to starting the attachment and one student from blocks two and three declined participation. Twenty two participants were therefore randomised to manikin only training and 22 to the hybrid training arm, (Figure 3 for the Trial Profile). All participants (100%) received their allocated intervention. Entry data was received for 44 (100%) students and outcome data for 43 (97%); one hybrid participant was lost to follow up due to illness on the day of assessment. Baseline

characteristics such as gender, prior hybrid simulation training, prior gynaecological and communication skills training were similar in the two arms (Table 1).

Following the objectively structured clinical examination, the hybrid trained cohort had higher technical scores (mean 23 vs 16.7; mean difference 6.3, 95% CI 3.0 to 9.6) and communication skills scores (mean 22.6 vs 15.9; mean difference 6.7, CI 4.8 – 8.5). The hybrid intervention showed a larger effect on communication skills scores than technical skills; see Table 2. Inter-rater reliability between the patient actor and examiner's assessment scores showed a significant and strong positive correlation; technical scores $r = 0.96$, $p=0.0001$ and communication scores $r = 0.86$, $p=0.0002$. Multivariate analysis revealed that these effects were independent of gender ($p=0.61$) and previous communication skills training ($p=0.71$).

Confidence in undertaking future pelvic examinations were similar in both the control and intervention groups after the OSCE; Table 2. Sub-analysis revealed that confidence had increased significantly in both groups before and after the initial training $p=0.0001$, $r = 0.56$ for the hybrid arm versus $p=0.0004$, $r = 0.51$ for the manikin only arm.

100% of participants completed the baseline survey prior to the initial training session. Four (9%) felt comfortable in undertaking consent for a gynaecological examination and two (4%) reported they understood the legal implications of not obtaining explicit consent or having a chaperone. 43 (98%) participants completed the post assessment DREEM survey, of whom 100% felt the training session met their learning style. Satisfaction scores for the method of training showed 20 participants (95%) in the hybrid group strongly agreed their

communication and procedural learning needs were met. Of the participants in the manikin only group, 10 (45%) agreed it met their learning needs and 12 (55%) felt the session was satisfactory in meeting their learning requirements. Comments from the hybrid participants showed they thought that the interaction with the patient made the experience 'more realistic' (19 participants), that it 'added lots to the learning' and 'having the actor was good, I feel more prepared and confident to undertake (*pelvic*) examinations on a patient now'.

Discussion:

Using objective clinical measures of pelvic examination skills, we found that the use of a hybrid model (manikin and patient actress) led not only to higher communication skill scores but also technical scores, when compared to students who were taught with manikins alone. Confidence scores were not significantly different but qualitative responses from the hybrid participants indicated that the integrated trainers improved the educational experience.

It is surprising that the addition of an actress alone to the pelvic model could show a statistically significant difference in the technical OSCE assessment scores rather than the communication scores alone. Formal feedback to the university suggests that the hybrid learners had an enhanced educational experience with greater satisfaction, enjoyment and value in the training method employed. This may then have cemented the students' short term acquisition of technical skill; effective learners are likely to have an enhanced concept of learning with improved self-regulation which guides them to set their own learning goals, decide on strategies to attain these goals and determine the effort they expend in achieving

these targets. Essentially, good feedback allows students to take control of their own learning, reflect on and assess progress towards their set goals.

The simple addition of an actress to the manikin may have helped integrate the academic content of the workshop into a situation that provided more meaning to the learner, which advocates of contextual learning believe can increase motivation to learn and assist students in acquiring skills more rapidly. The addition of the actress may have improved the quality of the feedback and also accounted for the higher communication skills scores in the hybrid cohort. Our findings are supported by Pugh *et al*²⁵ who compared students taught with a pelvic manikin, didactic controls and an electronic pelvic simulator. They demonstrated that communication scores were higher in the e-pelvis cohort, despite the lack of actors, by improving the quality of the feedback by the instructors, their peers and indeed the students themselves.

It is of upmost importance that training programmes teach the kinaesthetic component of pelvic examinations but also instil the importance of understanding women's attitudes towards these examinations. Intimate examinations can be embarrassing for both the patient and the health care professional²⁶. Traumatic experiences, fear of pain and embarrassment can lead to women refusing future examinations and affect attendance for cervical screening²⁷.

To address this, patients were recruited as teachers by medical schools to improve training. A randomised control trial revealed that students trained by these clinical teaching associates (CTAs) scored higher in both communication and technical skills ($p < 0.001$) than those taught

with a manikin alone.²⁴ Student anxiety and stress were also reduced by the use of CTAs.²⁸ The drawbacks of CTAs include high cost, healthy and slim volunteers (who are easier to examine and often have normal findings), the rigid scheduling requirements and the need for other teaching resources if students require additional practice.²⁹

Advantages of the hybrid model include the ability to vary the pelvic pathology within the manikins and the ease of organising multiple training sessions. Furthermore, our findings support the work of Kneebone *et al*^{22,30,31} and Higham *et al*¹⁷ who found that integrated models can effectively teach skills which are often taught separately. The use of hybrid simulation in an obstetric environment has been shown to improve procedural scores and clinical outcomes compared to didactic teaching alone^{18,32,33}, whilst bench model training for gynaecological procedural skills has been reported as both reliable and valid^{14,34}. Despite numerous studies investigating the ethics and legality of intimate examinations and the recent highlighting of patient safety concerns by medical regulatory authorities^{35,36}, many of the students in our study were unaware of the potential assault charge for examining a woman without explicit consent.

Our findings therefore have potential implications for undergraduate curricula as hybrid models provide an informal teaching environment where gynaecological competencies set by the university and regulatory authorities can be attained¹⁰, whilst emphasis can be placed on the ethical and legal responsibilities and phrasing of consent can be practiced without patient or student embarrassment. Furthermore, resources would be easy and cheap to source as the manikins and equipment for pelvic examinations will already be in use by the university.

Strengths of the study included double scoring of the clusters, standardization of the marking (which enhanced the quality of the outcome) and a 98% follow up rate which allowed for a balanced randomisation. Limitations of the study included a small number of clusters in each arm of the trial and the lack of a validated outcome assessment. A literature search revealed no such validated tools. The OSCE assessments were completed on a hybrid model which may have biased the hybrid taught group. However, 43 students examining a real patient under assessment standards, although more valid, would have been impractical and unethical. Although a standardised logbook was used for all undergraduates, some of the students may have completed more pelvic examinations than their peers and not documented this. It could be argued that the results were dependent upon the nature of the feedback given, not necessarily the simulation per se and showing structured videos could have been more cost effective and shown a similar change in the effect. However, all qualitative responses from the hybrid participants indicated that individualised feedback from the demonstrator and the actress, with further interactive training following this, maximised the immediate acquisition of skill.

A limitation of the methodology involved the incorporation of student self-assessment: studies have shown, at best, a moderate correlation between self-assessment marks and tutor marking. Students who are marked poorly by the faculty can overestimate their self-assessment scores, whilst high achievers can mark themselves more severely. Self-directed learning can therefore be affected by poor self-assessment and insight³⁷⁻³⁸. This may also help account for why technical scores were higher in the hybrid trained cohort; hybrid trained students had higher mean faculty scores which correlated with higher mean confidence scores

and this may have increased students' insight into domains that required improvement during the clinical attachment.

Conclusions:

Our findings have shown that hybrid models have significant educational value and a positive effect on the clinical performance of gynaecological examinations in an undergraduate setting. This study has also highlighted that a small change in teaching technique can make a significant difference to the students' learning experience. The incorporation of these hybrid models into medical school curricula should be cost effective and allow all undergraduates to attain their clinical competencies. Future studies should concentrate on whether integrated models lead to long term acquisition of skill and confidence. A comparison of clinical teaching associates to hybrid simulation would also be of interest, and should include cost-effectiveness.

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Author Contributions: Dr K Manley had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Manley, Edwards, Siassakos

Acquisition, analysis or interpretation of data: Manley

Drafting of the manuscript: Manley

Critical revision of the manuscript for important intellectual content: Manley, Edwards, Mears, Siassakos

Statistical analysis: Manley

Study Supervision: Mears, Siassakos

Ethical approval: This was granted by the University of Bristol Faculty of Medicine and Dentistry Committee for Ethics in September 2012 (Ref no 111279).

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Table 1: Participant Baseline Characteristics.

Demographic	Manikin Only Intervention n = 22	Hybrid Model Intervention n = 21
Age (median + IQR)	23 (0)	23 (0.5)
Male	11	12
First Language English	21	20
Undergraduate Communication Skills Workshop in Year 3.	22	21
Desire to follow a career in Women's Health	2	3

Table 2: Technical and Communication Skills Scores.

	Manikin (n=22): mean score (CI)	Hybrid (n=21): mean score (CI)	Mean Difference (95% CI)	p-value	Effect size
Overall ability	3.09 (2.68 to 3.49)	4.48 (4.10 to 4.84)	1.39 (0.8 to 1.9)	<0.00001	0.63
Technical Score	16.7 (14.7 to 18.6)	23 (20.1 to 25.8)	6.3 (3.0 to 9.6)	0.0002	0.51
Communication Skills Score	15.9 (14.4-17.3)	22.6 (21.2-23.8)	6.7 (4.8 to 8.5)	<0.0001	0.74
Confidence	23.5 (21.4 to 25.5)	25.6 (22.6 to 28.4)	2.1	0.10	0.18

Figure 3: Trial Profile

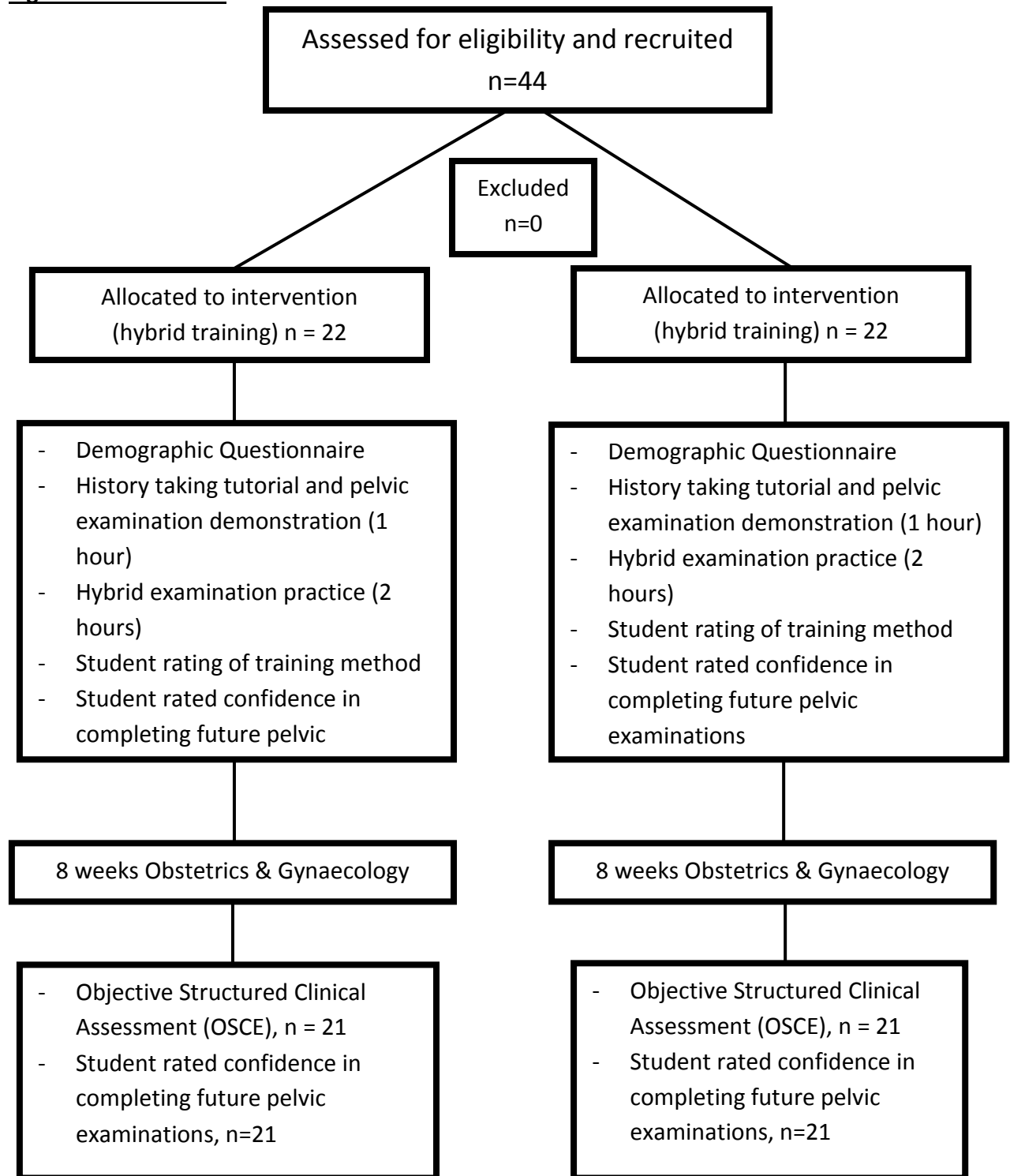
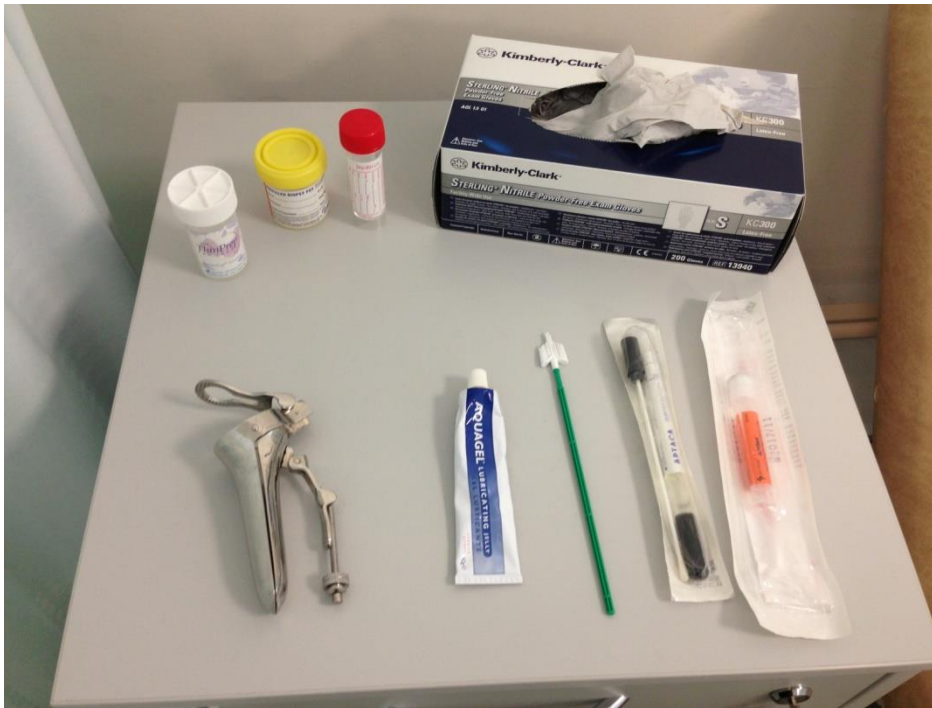


Figure 1: The Hybrid Model



Figure 2: Equipment Layout for the assessment.



Supplementary 1: Crib Sheet for the Initial Training Session.

Competency	Tick if discussed
Explain the purpose of the procedure and how it will be undertaken in layman's terms.	
The woman should be given the choice about the gender, pace and position for the examination.	
Obtain verbal consent.	
Offer a chaperone and consider patient dignity (closed room that cannot be entered).	
Be aware of, and sensitive to, cultural or religious expectations – Muslim and Hindu women prefer female doctors if possible. Many religions incorporate taboos about examinations during menstruation.	
Patient safety: wash hands and use gloves.	
Remain alert to verbal and non-verbal indications of distress from the patient.	
Practice assembling the equipment to prevent fumbling and causing distress.	
Undertake a gentle abdominal examination, speculum, smear, swabs and bimanual on the model.	
Protect the woman's privacy and modesty: covering up during and after the examination.	
Patient safety: disposal of the instruments.	
Effective communication about the findings and follow up when modesty is attained.	

Supplementary 2: Scoring sheet for confidence in undertaking a pelvic examination

1. *How ready or 'energised' do you feel to carry out a pelvic examination?*

Not at all ready / energised 1 2 3 4 5 6 very energised

2. *How confident do you feel to carry out a pelvic examination?*

Not at all confident 1 2 3 4 5 6 very confident

3. *How well do you think you can perform a pelvic examination compared to others at your stage?*

Not well at all 1 2 3 4 5 6 very well

4. *How helpful is the activity you have just been performing in preparing you to perform a pelvic examination?*

Not helpful at all 1 2 3 4 5 6 very helpful

5. *How easily can you 'see' yourself performing a pelvic examination?*

Not easily at all 1 2 3 4 5 6 very easily

6. *How vivid and clear are the images of a pelvic examination in your mind?*

Not vivid / clear at all 1 2 3 4 5 6 very vivid /clear

7. *How easily can you 'feel' yourself performing a pelvic examination?*

Not easily at all 1 2 3 4 5 6 very easily

8. *How easily would you be able to talk to someone through the steps of a pelvic examination?*

Not easily at all 1 2 3 4 5 6 very easily

Supplementary 3: OSCE assessment form and scoring criteria

ELEMENT ASSESSED	SCORE
1. Introduction (maintain dignity , chaperone)*	
2. Explained procedure and gained consent*	
3. Assessed patient's needs before the procedure (do they understand what is involved, have they had procedure before)*	
4. Preparation for the procedure (check equipment ready and in order before starting examination)**	
5. Abdominal Palpation**	
6. Atraumatic insertion of speculum & visualisation of the cervix**	
7. Bimanual examination (reports anteverted, mobile, smooth uterus and no adnexal masses).**	
8. Correctly takes and labels swabs.**	
9. Maintenance of asepsis (wash hands, gloves)**	
10. Awareness of patient's needs during the procedure*	
11. Closure of procedure including explanation of follow up care (when results ready and how they will be sent)*	
12. Clinical safety (offer chaperone, door, cover up post procedure and dispose of dirty equipment)*	
13. Professionalism	
14. Overall ability to perform the procedure	

Key: *Communication skills scores **Technical Skills Scores

SCORING CRITERIA

1 = well below expectations (did not perform)

2 = below expectations (completed but awkward and tentative)

3 = satisfactory (completed but some unnecessary moves)

4 = safe and competent performance

5 = above expectations

6 = well above expectations (economy of movement, maximum efficacy, completed with ease)